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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,587	02/12/2001	Anders Hjelholt Pedersen	0212us310	9481

30560 7590 02/24/2004

MAXYGEN, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
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EXAMINER

TELLER, ROY R

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/782,587

Applicant(s)

PEDERSEN ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 68,69,75-77,81-83,86-91,93,94 and 103-112 is/are pending in the application.
- 4a) Of the above claim(s) 75-77,81-83 and 106-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68,69,86-91,93,94 and 103-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12102003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This office action is in response to the communication, received 12/10/03, in which applicant amended claims 68-69, 86-87, 90, and 93; and cancelled claims 70-74, 78-80, 84-85, 92, 95-102, 113-116.

Claims 75-77, 81-83, and 106-112 are withdrawn as reading on non-elected inventions.

Claims 68-69, 86-91, 93-94, and 103-105 are pending.

#### ***Information Disclosure Statement***

The supplemental information disclosure statement, received 12/10/03, has been considered. A signed copy is enclosed hereto.

#### ***Claim Rejections - 35 USC § 112***

Upon further consideration, the rejection under 35 U.S.C., first paragraph of claim 68 is withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The rejection under 35 U.S.C. 103(a) of claims 68-69, 86-91, 93-94, and 103-105 is maintained. Applicant's arguments have been carefully considered but are not deemed to be persuasive of error in the rejection.

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Applicant contends that a *prima facie* case of obviousness was not met with respect to the cited reference. Applicant contends that the examiner's office action does not point with any particularity to any teaching or suggestion in Berkner (USPN 5,861,374) which would motivate one of skill to make a conjugate comprising a polypeptide comprising an amino acid sequence which differs from the hFVII or hFVIIa sequence ID NO:1 in 1-15 amino acid residues. The examiner contends that Berkner teaches pharmaceutical compositions of modified factor VII that are used to treat a variety of coagulation-related disorders, see abstract. Berkner discloses SEQ ID NO:2, which has a 99.1% query match with SEQ ID NO:1 of the instant application. This query match differs by 4 amino acids from the claimed instant sequence. The instant specification recites " In order to avoid too much disruption of the structure and function of the parent molecule the polypeptide part of the conjugate will typically have an amino acid sequence having more than 90% identity with SEQ ID NO:1, preferably more than 95%, such as more than 96%. In particular, the polypeptide part of the conjugate will typically have an amino acid sequence having more than 97% identity with SEQ ID NO:1, such as more than 98%, more than 99%...", see page 18, lines 30-35.

### ***Conclusion***

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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2/20/04

RT



CHRISTOPHER R. TATE  
PRIMARY EXAMINER